[F1 ANNEX I

CHEMICAL, PHARMACEUTICAL AND ANALYTICAL STANDARDS, SAFETY AND RESIDUE TESTS, PRE-CLINICAL AND CLINICAL TRIALS IN RESPECT OF TESTING OF VETERINARY MEDICINAL PRODUCTS

Textual Amendments

F1 Substituted by Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use (Text with EEA relevance).

INTRODUCTION AND GENERAL PRINCIPLES

1. The particulars and documents accompanying an application for marketing authorisation pursuant to Articles 12 to 13d shall be presented in accordance with the requirements set out in this Annex and shall take into account the guidance published by the Commission in *The rules governing medicinal products in the European Union*, Volume 6 B, Notice to applicants, Veterinary medicinal products, Presentation and Contents of the Dossier.**]**